Laparoscopic supracervical hysterectomy versus endometrial ablation for women with heavy menstrual bleeding (HEALTH)

Citation for published version:
HEALTH Study Group 2019, 'Laparoscopic supracervical hysterectomy versus endometrial ablation for women with heavy menstrual bleeding (HEALTH): a parallel-group, open-label, randomised controlled trial', *The Lancet*. https://doi.org/10.1016/S0140-6736(19)31790-8

Digital Object Identifier (DOI):
10.1016/S0140-6736(19)31790-8

Link:
Link to publication record in Edinburgh Research Explorer

Document Version:
Version created as part of publication process; publisher's layout; not normally made publicly available

Published In:
The Lancet

Laparoscopic supracervical hysterectomy versus endometrial ablation for women with heavy menstrual bleeding (HEALTH): a parallel-group, open-label, randomised controlled trial

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Summary

Background Heavy menstrual bleeding affects 25% of women in the UK, many of whom require surgery to treat it. Hysterectomy is effective but has more complications than endometrial ablation, which is less invasive but ultimately leads to hysterectomy in 20% of women. We compared laparoscopic supracervical hysterectomy with endometrial ablation in women seeking surgical treatment for heavy menstrual bleeding.

Methods In this parallel-group, multicentre, open-label, randomised controlled trial in 31 hospitals in the UK, women younger than 50 years who were referred to a gynaecologist for surgical treatment of heavy menstrual bleeding and who were eligible for endometrial ablation were randomly allocated (1:1) to either laparoscopic supracervical hysterectomy or second generation endometrial ablation. Women were randomly assigned by either an interactive voice response telephone system or an internet-based application with a minimisation algorithm based on centre and age group (<40 years *vs* ≥40 years). Laparoscopic supracervical hysterectomy involves laparoscopic (keyhole) surgery to remove the upper part of the uterus (the body) containing the endometrium. Endometrial ablation aims to treat heavy menstrual bleeding by destroying the endometrium, which is responsible for heavy periods. The co-primary clinical outcomes were patient satisfaction and condition-specific quality of life, measured with the menorrhagia multi-attribute quality of life scale (MMAS), assessed at 15 months after randomisation. Our analysis was based on the intention-to-treat principle. The trial was registered with the ISRCTN registry, number ISRCTN49013893.

Findings Between May 21, 2014, and March 28, 2017, we enrolled and randomly assigned 660 women (330 in each group). 616 (93%) of 660 women were operated on within the study period, 588 (95%) of whom received the allocated procedure and 28 (5%) of whom had an alternative surgery. At 15 months after randomisation, more women allocated to laparoscopic supracervical hysterectomy were satisfied with their operation compared with those in the endometrial ablation group (270 [97%] of 278 women *vs* 244 [87%] of 280 women; adjusted percentage difference 9·8, 95% CI 5·1–14·5; adjusted odds ratio [OR] 2·53, 95% CI 1·83–3·48; p<0·0001). Women randomly assigned to laparoscopic supracervical hysterectomy were also more likely to have the best possible MMAS score of 100 than women assigned to endometrial ablation (180 [69%] of 262 women *vs* 146 [54%] of 268 women; adjusted percentage difference 13·3, 95% CI 3·8–22·8; adjusted OR 1·87, 95% CI 1·31–2·67; p=0·00058). 14 (5%) of 309 women in the laparoscopic supracervical hysterectomy group and 11 (4%) of 307 women in the endometrial ablation group had at least one serious adverse event (adjusted OR 1·30, 95% CI 0·56–3·02; p=0·54).

Interpretation Laparoscopic supracervical hysterectomy is superior to endometrial ablation in terms of clinical effectiveness and has a similar proportion of complications, but takes longer to perform and is associated with a longer recovery.

Funding UK National Institute for Health Research Health Technology Assessment Programme.

Published **Online** September 12, 2019 http://dx.doi.org/10.1016/S0140-6736(19)31790-8

See **Online/Comment** http://dx.doi.org/10.1016/S0140-6736(19)32086-0

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Introduction

Heavy menstrual bleeding, which affects a quarter of women in the UK,[1] accounts for around a fifth of all hospital gynaecology referrals and has a profound effect on quality of life.[2] In the USA, the condition leads to a three times increase in hospitalisation compared with age-matched control patients who do not have heavy menstrual bleeding[3] and imposes a major economic burden on society because of the costs of treatment and loss of productivity.[4] The initial approach to treatment of heavy menstrual bleeding is medical, but treatment failure is high. Up to 77% of women on oral drugs and 42% of those using the levonorgestrel intrauterine system (Mirena; Bayer, Leverkusen, Germany) need to undergo surgical treatment within 5 years.[5] More than a third (38%) of women referred to an English National

Research in context

Evidence before this study

Heavy menstrual bleeding is a common problem that affects around 1·5 million women in England and Wales and has a substantial negative effect on their quality of life. The National Institute for Health and Care Excellence recommends endometrial ablation or hysterectomy as surgical options for women with heavy menstrual bleeding that is resistant to medical treatment. We searched PubMed and the Cochrane Library in 2013 and updated the search on Dec 27, 2018, with the search terms "heavy menstrual bleeding", "hysterectomy", "endometrial ablation", "randomised trial", and "systematic review", with no language restrictions. An individual participant data meta-analysis published in 2014 showed that fewer women are dissatisfied with conventional hysterectomy than with endometrial ablation, but the former option is more invasive, involves a longer hospital stay, and prolonged recovery time. A health economic model based on these data showed that hysterectomy was more cost-effective. A Health Technology Assessment monograph from the same research group indicated that 25% of all women undergo subsequent gynaecological surgery following endometrial ablation, with just under a fifth requiring hysterectomy. These findings are consistent with those of a relevant Cochrane review, which concluded that the optimal surgical treatment for heavy menstrual bleeding unresponsive to medical treatment might be hysterectomy, but the effectiveness of this treatment needs to be balanced against its invasiveness and increased short-term and long-term morbidity.

Added value of this study

This trial showed that a less invasive alternative to conventional hysterectomy—laparoscopic supracervical hysterectomy—was more effective than endometrial ablation without increasing surgical risk. Laparoscopic supracervical hysterectomy was clinically superior to endometrial ablation in terms of satisfaction (270 [97%] of 278 patients *vs* 244 [87%] of 280 patients; adjusted percentage difference 9·8, 95% CI 5·1–14·5; adjusted odds ratio [OR] 2·53, 95% CI 1·83–3·48; p<0·0001) and quality of life as assessed by the menorrhagia multi-attribute quality-of-life scale (adjusted OR 1·87, 95% CI 1·31–2·67; p=0·00058). Serious adverse event numbers were low and similar for both procedures.

Implications of all the available evidence

This study shows that a less invasive form of hysterectomy can result in high satisfaction associated with removal of the uterus and low morbidity, which is similar to less invasive surgery, such as endometrial ablation.

Health Service (NHS) hospital between April, 2009, and March, 2012, with heavy menstrual bleeding received surgery,[2] and in the USA the corresponding figure was 63%.[3]

The two most common surgical treatments for heavy menstrual bleeding are endometrial ablation, where the endometrium is thermally destroyed but the uterus is preserved, and hysterectomy, where the uterus is removed.[6] Endometrial ablation does not require surgical incisions and newer (second generation) techniques are simple to learn, quick to perform, and associated with rapid recovery and early return to work.[7] Various energy sources can be used for endometrial ablation, but the most common are radiofrequency energy (Novasure; Hologic, Marlborough, MA, USA) or heated, fluid filled balloons.[8]

Hysterectomy can be done in several different ways, but total hysterectomy (ie, removal of the uterus and cervix) by open surgery remains the most widely used technique in the UK.[2] Total laparoscopic hysterectomy avoids large abdominal incisions, requires a shorter hospital stay, and facilitates quicker recovery. However, this procedure takes longer, requires advanced laparoscopic skills, and has more complications compared with conventional open surgery.[9] Laparoscopic supracervical hysterectomy only requires removal of the uterine body, which is the main source of heavy menstrual bleeding. This strategy offers a less complex alternative that avoids difficult surgical dissection around the cervix and bladder, reducing the risk of urinary tract injury and bleeding.[10] The availability of newer surgical equipment has simplified laparoscopic supracervical hysterectomy and this fact, combined with improvements in laparoscopic training, has made the procedure accessible to most gynaecologists.

Although endometrial ablation is an effective, minimally invasive, and uterine sparing treatment for heavy menstrual bleeding, almost 20% of women who have this treatment will ultimately require a hysterectomy for relief of their symptoms.[11] An individual participant data meta-analysis of randomised trials showed that total hysterectomy was superior to endometrial ablation in terms of clinical and cost effectiveness,[12,13] but was associated with a longer hospital stay, slower recovery, and a higher risk of surgical complications.[14] Furthermore, total hysterectomy could predispose a woman to development of bladder symptoms, such as urgency and stress incontinence.[11,15,16] Two small randomised trials suggested that laparoscopic supracervical hysterectomy could achieve outcomes similar to those after total hysterectomy but with quicker recovery and fewer complications.[17,18] A Cochrane review on this topic recommended a head-to-head comparison of second generation endometrial ablation with more recent types of hysterectomy, including laparoscopic supracervical hysterectomy.[14] We aimed to compare the clinical effectiveness of laparoscopic supracervical hysterectomy with endometrial ablation in women opting for surgical treatment for heavy menstrual bleeding.

www.thelancet.com **Published online September 12, 2019 http://dx.doi.org/10.1016/S0140-6736(19)31790-8**

Methods

Study design and participants

The HEALTH study was a multicentre, parallel-group, open-label, randomised controlled trial in 31 hospitals in the UK. The trial protocol has been published previously.[19] Participants were women younger than 50 years with no desire for (further) children who were referred to a gynaecologist for surgical treatment of heavy menstrual bleeding. Inclusion criteria were eligibility for endometrial ablation (fibroids <3 cm, uterine cavity size <11 cm, and absence of endometrial pathology on biopsy) and normal cervical cytology. Women were excluded if they had undergone a previous endometrial ablation, if laparoscopic surgery was contraindicated, or if they were unable to give informed consent or complete trial paperwork.

Patients gave written informed consent for inclusion in the study. The study was centrally approved by the North of Scotland Research Ethics Service (reference no 13/NS/0155) for all 31 centres and was done according to the principles of good clinical practice provided by research governance guidelines.

Randomisation and masking

Women were randomly assigned (1:1) to laparoscopic supracervical hysterectomy or second generation endometrial ablation by either an Interactive Voice Response telephone system or an internet-based application with a minimisation algorithm based on centre and age group (<40 years *vs* ≥40 years). Participants were enrolled by dedicated research nurses who used a remote web-based randomisation application at the Centre for Healthcare Randomised Trials (CHaRT; University of Aberdeen, Aberdeen, UK) for group allocation. The research nurses were not involved in the collection of primary outcome data. Surgeons and participants could not be masked to the allocated procedure because of the nature of the interventions.

Procedures

After randomisation, participants were placed on the NHS surgical waiting list for the appropriate treatment. As per Scottish and UK Government guidelines, it was anticipated that treatment would occur within 12–18 weeks of random assignment.[20,21] Principal investigators from all 31 participating hospitals were members of the British Society of Gynaecological Endoscopy. Each responsible surgeon was certified competent for both procedures as per usual NHS and good clinical practice requirements, but the technique used was not modified for the purposes of the trial. All other aspects of care were left to the discretion of the responsible surgeon.

Laparoscopic supracervical hysterectomy involves laparoscopic (keyhole) surgery to remove the upper part of the uterus (the body) containing the endometrium. As the cervix is not removed, complex dissection, which potentially increases the risk of injury to surrounding structures like the bladder, ureters, and blood vessels, can be avoided.[9,22] Cervical cancer screening is still required and, although most women will cease to have periods after the procedure, light menstrual bleeding or cyclical spotting can occur in 5–20% of women.[23,24]

The body of the uterus is detached from the cervix usually with a monopolar or bipolar wire loop after sealing the uterine vessels. The body is removed through a 10–12-mm port sited either within the umbilicus or suprapubically with a power morcellator that converts the specimen into strips of tissue. This process can be done inside a bag to prevent spread of fragmented tissue within the peritoneal cavity. Alternatively, the complete unmorcellated specimen can be removed through an internal incision at the top of the vagina (culdotomy).

Endometrial ablation aims to treat heavy menstrual bleeding by destroying the endometrium, which is responsible for heavy periods. First generation endometrial ablation techniques involve an operating hysteroscope and a loop, ball, or laser energy and, although effective, are difficult to learn and highly operator dependent. The more commonly used second generation endometrial ablation techniques involve devices that are inserted into the uterine cavity that, when activated, will destroy the endometrium and superficial myometrium, containing endometrial glands, up to 6 mm. Other than the actual insertion of the device into the uterine cavity, these techniques tend not to be operator dependent.

Second generation procedures used in the UK and recommended by The National Institute for Health and Care Excellence (NICE)[6] include thermal balloon endometrial ablation and radiofrequency energy (Novasure). Thermal balloon endometrial ablation is achieved by means of a silicone balloon that is introduced through the cervix into the uterine cavity. The balloon fills and expands to conform to the inside of the uterine cavity, compressing the endometrium. Hot fluid circulating within the balloon ensures endometrial destruction and the temperature and duration of treatment is carefully controlled electronically by means of a computer attached to the device. Novasure uses radiofrequency energy delivered through an intrauterine mesh electrode that expands after insertion through the cervix to fit the shape of the uterine cavity. The energy required is calculated by the device and treatment times are under 90 s. These treatments substantially reduce menstrual bleeding and result in complete cessation of bleeding in up to 50% of women.[8] Second generation endometrial ablation can be done as a day case procedure, either under general or local anaesthetic. Although suitable for use in the outpatient setting, most endometrial ablations (94%) are done in operating theatres in the UK.[25]

The local research team at each centre collected intra-operative and post-operative data at the time of the randomly assigned procedure and completed a short case report form for any related hospital readmissions during the follow-up period. Participant-reported

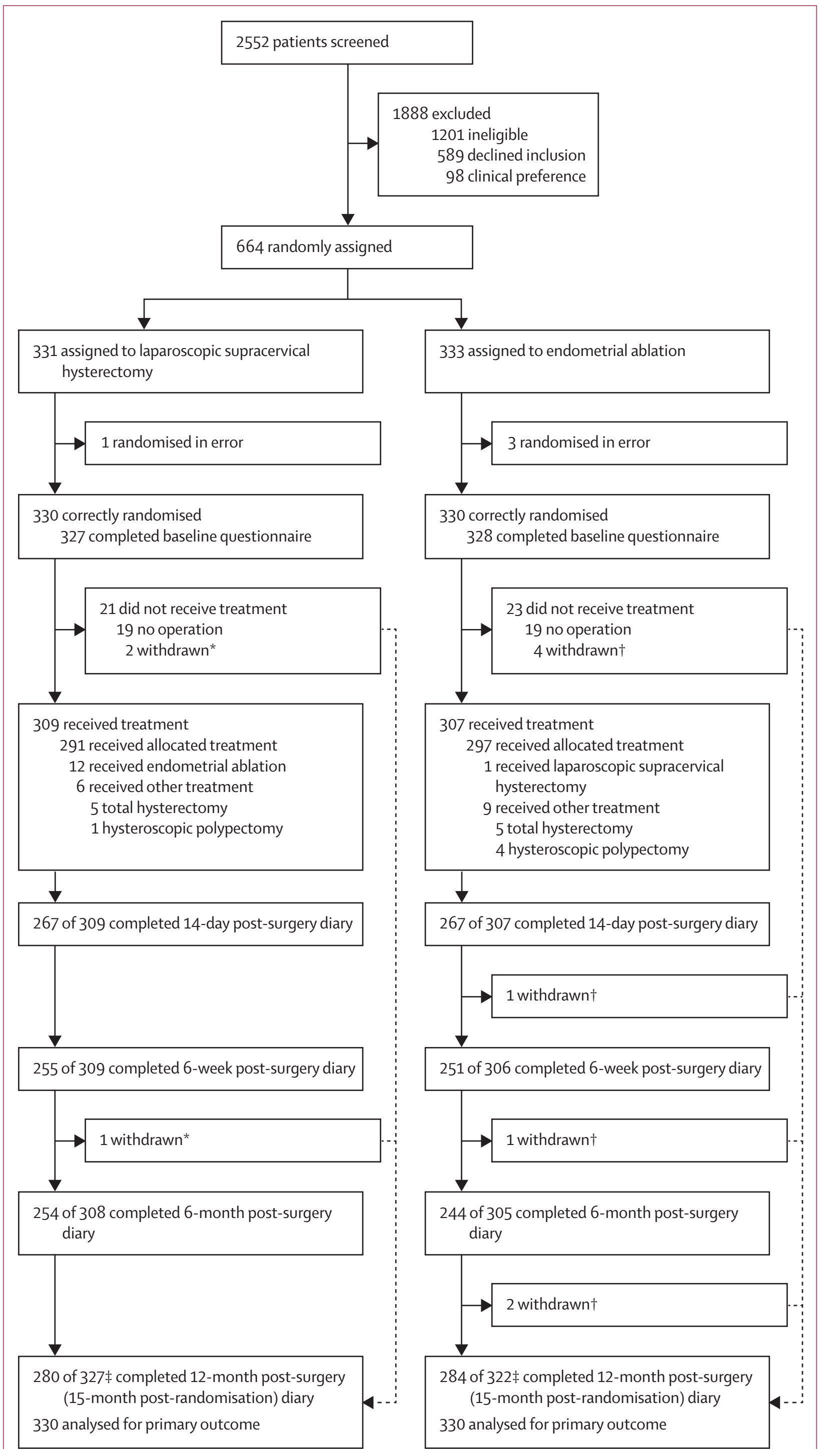

***Figure:* Trial profile**

*Reasons were unwillingness to have surgery (one patient), private treatment (one patient), and no reason given (one patient). †Reasons were unwillingness to have surgery (two patients), requested a different operation (two patients), family illness (one patient), moved abroad (one patient), and did not want to complete questionnaires (two patients). ‡Excluding withdrawn patients but including the 19 patients in each group who did not receive treatment.

outcomes were assessed by self-completed questionnaires at baseline (before surgery), 6 weeks, and 6 months after surgery, and 15 months after randomisation. A self-completed 14-day diary was also collected. We sent non-responders up to two reminders by either post, email, telephone, or text message depending on the woman's preferred method of communication. Pathology results for all endometrial biopsies and uterine specimens were also obtained.

We had a 15-month follow-up period after randomisation to accommodate the 12–18 week waiting time for treatment. Our intention was that participants would complete their primary outcome questionnaire (triggered 15 months after randomisation) approximately 12 months after surgery to facilitate comparisons with outcomes from other similar trials in the literature.

Outcomes

The co-primary clinical outcomes assessed at 15 months after randomisation were patient satisfaction, measured on a six point Likert scale (from totally satisfied to totally dissatisfied),[26] and the menorrhagia multi-attribute quality of life scale (MMAS), which provides a condition-specific quality of life outcome[27] ranging from 0 (worst possible health state) to 100 (best possible health state) based on six items, measured at 15 months after randomisation.

Secondary outcome measures were MMAS at 6 months after surgery; patient-reported satisfaction at 6 months after surgery; self-reported pain score at days 1–14 and 6 weeks after surgery; acceptability of treatment at 6 weeks after surgery; menstrual outcomes at 6 months after surgery and 15 months after randomisation; symptom diary on days 1 to 14 after surgery; generic health-related quality of life (assessed with the short form 12 [SF-12; 0 represents the worst possible quality of life and 100 the best possible quality of life] comprising a physical component score and mental component score, and EuroQol Group 5 dimension health status questionnaire [EQ-5D-3L; utility score: –0·59 represents the worst possible quality of life and 1·00 the best possible quality of life; visual analogue scale: 0 represents the worst imaginable health state and 100 the best possible health state] at 6 weeks, 6 months after surgery and 15 months after randomisation); duration of operation; peri-operative complications and recovery details, including analgesia requirements, time for discharge, and need for additional gynaecological surgery by 15 months after randomisation; and wider societal costs associated with changes in productivity based on information and the time taken to return to normal activities combined with questions on work productivity delivered during the follow-up period.

The co-ordinating study team was notified of adverse events either directly by local researchers or through entries in follow-up questionnaires completed by participants. The local research team verified suspected adverse events where possible. We did not record unrelated

www.thelancet.com **Published online September 12, 2019 http://dx.doi.org/10.1016/S0140-6736(19)31790-8**

adverse events. Serious adverse events were defined by use of standard classifications.[28]

Statistical analysis

We powered the HEALTH study to detect a difference in satisfaction of 8% (assuming 95% overall satisfaction after total hysterectomy and 87% overall satisfaction after endometrial ablation).[12] We required outcome data on 292 participants for 90% power, assuming a two-sided significance level of 5%, inflated to 324 participants to allow for 10% attrition in the primary outcome. To retain a significance level of 5% for the primary outcome analysis, we specified a hierarchy for testing the primary outcomes—MMAS was only examined if the result for patient satisfaction was statistically significant ($p<0\cdot05$). This trial also had more than 90% power to detect a ten-point difference in MMAS, assuming an SD of 33 units.

We used appropriate descriptive statistics to summarise data at all timepoints, with mean (SD) or median (IQR) for continuous data, and frequencies and percentages for categorical data. Our analysis was based on the intention-to-treat principle—participants were analysed by randomised group and not by the treatment received.

We used ordinal logistic regression to analyse both co-primary outcomes. This decision was made after discussion with the independent data monitoring committee, which met on Oct 17, 2017, after they raised concerns about the appropriateness of the methods in our original analysis plan given the distribution of outcome data in an interim report (without considering any emerging treatment effect). For full details of the rationale for this change and the implications for power in the revised analysis plan see the appendix (pp 1–24). Analysis of patient satisfaction used the following four categories: totally satisfied, generally satisfied, fairly satisfied, and fairly, generally, or totally dissatisfied. MMAS was coded as an ordinal variable with the following four categories: ≤50, 51–75, 76–99, and 100 (maximum score), because of the extreme skewness of this outcome at follow-up. We checked the proportional odds assumption was appropriate by examining the odds ratios (ORs) from binary logistic regression for the three binary splits of the data (for satisfaction: totally satisfied *vs* other, totally or generally satisfied *vs* other, and satisfied *vs* dissatisfied; for MMAS: 0–99 *vs* 100, 0–75 *vs* 76–100, and 0–50 *vs* 51–100) and by Brant test with a significance threshold of $p<0\cdot001$. We analysed secondary outcomes with generalised linear models with appropriate link functions for the distribution of the outcome. We used repeated measures regression for the pain score recorded in the patient diary in the first two weeks after surgery. Details of categories used in ordinal logistic regression models for skewed continuous variables are shown in the appendix (pp 41–42).

We did not make any adjustments for multiple testing. Analyses of all primary and secondary outcomes were adjusted for the minimisation variables age group and centre (treated as a random effect) and for a relevant baseline score if available. We did several sensitivity and subgroup analyses for the primary outcomes. These included an unadjusted ordinal logistic regression analysis, binary logistic regression analyses for each split of the data, analyses using multiple imputation, a per protocol analysis, an analysis restricted to operations done by a consultant, and a linear regression analysis for MMAS (appendix pp 25–26, 30–32). 95% CIs are provided for all measures of effect.

For the co-primary outcomes, we also did exploratory subgroup analyses for the following prespecified variables: uterine cavity length (≤8 cm *vs* >8 cm), menstrual pain (dysmenorrhea) at baseline (severe or crippling pain *vs* other categories), patient age (<40 years *vs* ≥40 years), and presence or absence of fibroids. These tests were done by including a treatment by subgroup interaction term in the corresponding ordinal logistic regression model.

We used Stata 15.1 for all analyses. The trial was registered with the ISRCTN registry, number ISRCTN49013893.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between May 21, 2014, and March 28, 2017, we enrolled and randomly assigned 660 women (330 in each group;

See Online for appendix

	Laparoscopic supracervical endometrial ablation (n=330)	Endometrial ablation (n=330)
Age (years)	42 (5)	42 (5)
Body-mass index (kg/m²)	29·1 (5·6) [309]	29·0 (5·3) [304]
Pre-operative haemoglobin (g/L)	131·0 (13·1) [306]	130·1 (12·6) [282]
Number of caesarean sections	0 (0–1) [326]	0 (0–1) [327]
Very heavy periods with clots and flooding	261/327 (80%)	259/327 (79%)
Periods with severe dysmenorrhoea	170/326 (52%)	160/326 (49%)
Pain at intercourse	193/299 (65%)	186/306 (61%)
Bladder symptoms (urinary urgency, stress incontinence, or both)	188/323 (58%)	178/325 (55%)
Baseline outcome scores		
Menorrhagia multi-attribute quality of life scale total score*	28·6 (14·7–43·7) [323]	29 (15·7–47·7) [321]
EQ-5D-3L†	0·76 (0·66–1·00) [319]	0·79 (0·69–1·00) [322]
EQ-5D-3L visual analogue scale‡	70 (50–85) [317]	70 (52–85) [321]
SF-12 physical component summary§	45·0 (9·0) [318]	44·9 (9·7) [321]
SF-12 mental component summary§	37·2 (11·0) [318]	38·7 (11·6) [321]

Data are mean (SD), n/N (%), or median (IQR). N in square brackets indicates the valid N for continuous data where there were missing data at baseline. EQ-5D-3L=EuroQol questionnaire, five dimensions, three levels. SF-12=short form 12.

Table 1: **Baseline characteristics**

figure). The study groups were similar at baseline in terms of age, severity, and duration of symptoms (table 1). 616 (93%) of 660 women were operated on within the study period, 588 (95%) of whom received the allocated procedure and 28 (5%) of whom had an alternative surgery.

At 15 months after randomisation, more women allocated to laparoscopic supracervical hysterectomy were satisfied with their operation compared with those in the endometrial ablation group (270 [97%] of 278 women *vs* 244 [87%] of 280 women; adjusted percentage difference 9·8, 95% CI 5·1–14·5; adjusted OR 2·53, 1·83–3·48; p<0·0001; table 2). Women randomly assigned to laparoscopic supracervical hysterectomy were also more likely to have the best possible MMAS score of 100 than were women assigned to endometrial ablation (180 [69%] of 262 women *vs* 146 [54%] of 268 women; adjusted percentage difference 13·3, 95% CI 3·8–22·8; adjusted OR 1·87, 1·31–2·67; p=0·0058; table 2).

Fewer women in the laparoscopic supracervical hysterectomy group continued to have periods (adjusted OR 0·32, 95% CI 0·21–0·48; p<0·0001), cyclical period-like pelvic pain (0·31, 0·22–0·44; p<0·0001), or pain during intercourse (0·61, 0·41–0·91; p=0·015) compared with women in the endometrial ablation group. We observed no clinically or statistically significant difference in the proportion of women reporting bladder symptoms (urinary urgency, stress, or mixed incontinence; 0·97, 0·73–1·29; p=0·83; table 2).

Women randomly assigned to endometrial ablation reported higher EQ-5D-5L utility and SF-12 physical component scores 6 weeks after surgery (appendix pp 35–36). By 15 months after randomisation, women in the laparoscopic supracervical hysterectomy group had better scores for the EQ-5D-3L visual analogue scale (adjusted OR 1·50, 95% CI 1·12 to 1·99; p=0·0057) and the SF-12 mental component score (adjusted mean difference 2·47, 1·07 to 3·87; p=0·0012; table 2). We observed no clinically or statistically significant differences between the groups regarding the EQ-5D-3L utility score (adjusted OR 1·21, 0·89 to 1·64; p=0·23) or SF-12 physical component score (adjusted mean difference 1·08, –0·65 to 2·81; p=0·21) at 15 months (table 2). All 6-months post procedure data are reported in the appendix (pp 35–42) and were similar to the primary outcome measures at 15 months after randomisation.

Laparoscopic supracervical hysterectomy was associated with increased operating times and length of

	Laparoscopic supracervical hysterectomy (n=330)	Endometrial ablation (n=330)	Adjusted effect size (95% CI)	p value
Satisfaction	..	..	2·53* (1·83 to 3·48)	<0·0001
Totally satisfied	211/278 (76%)	158/280 (56%)	..	..
Generally satisfied	40/278 (14%)	57/280 (20%)	..	..
Fairly satisfied	19/278 (7%)	29/280 (10%)	..	..
Fairly, generally, or totally dissatisfied	8/278 (3%)	36/280 (13%)	..	..
Overall satisfaction (fairly, generally, or totally satisfied)	270/278 (97%)	244/280 (87%)	9·80† (5·08 to 14·51)	0·00089
Total menorrhagia multi-attribute quality-of-life score	..	..	1·87* (1·31 to 2·67)	0·00058
100	180/262 (69%)	146/268 (54%)	..	..
76–99	50/262 (19%)	59/268 (22%)	..	..
51–75	17/262 (6%)	34/268 (13%)	..	..
0–50	15/262 (6%)	29/268 (11%)	..	..
Secondary outcomes				
Continuing periods	52/277 (19%)	117/277 (42%)	0·32* (0·21 to 0·48)	<0·0001
Cyclical (period-like) pelvic pain	71/224 (32%)	118/196 (60%)	0·31* (0·22 to 0·44)	<0·0001
Pain at intercourse	62/213 (29%)	80/204 (39%)	0·61* (0·41 to 0·91)	0·015
Bladder symptoms	116/232 (50%)	113/223 (51%)	0·97* (0·73 to 1·29)	0·83
Recommend treatment to friend	263/271 (97%)	246/280 (88%)	4·52* (2·14 to 9·53)	<0·0001
Quality of life				
EQ-5D-3L utility score	1·00 (0·73–1·00) [281]	0·85 (0·72–1·00) [281]	1·21* (0·89 to 1·64)	0·23
EQ-5D-3L visual analogue scale	85 (70–90) [279]	80 (65–90) [282]	1·50* (1·12 to 1·99)	0·0057
SF-12 physical component score	53·5 (8·9) [219]	52·4 (9·0) [216]	1·08‡ (–0·65 to 2·81)	0·21
SF-12 mental component score	48·5 (11·2) [219]	46·6 (11·1) [216]	2·47‡ (1·07 to 3·87)	0·0012

Data are n/N (%), median (IQR), or mean (SD), unless otherwise indicated. N in square brackets indicates the denominator or valid N where there was missing data. All estimates adjusted for age group, centre, and baseline score (where applicable). EQ-5D-3L=EuroQol questionnaire, five dimensions, three levels. SF-12=short form 12. *Odds ratio from ordinal logistic regression or binary logistic regression. †Adjusted difference in percentages for those satisfied (all categories) versus other. ‡Difference in means from linear regression.

Table 2: **Primary and selected secondary outcomes at 15 months after randomisation**

hospital stay (table 3). 99 (32%) of 306 women allocated to laparoscopic supracervical hysterectomy had a post-operative hospital stay of more than 24 h compared with 16 (5%) of 303 women in the endometrial ablation group. More women randomly assigned to laparoscopic supracervical hysterectomy were noted to have subserosal or intramural fibroids during surgery (table 3). 14 (5%) of 309 women in the laparoscopic supracervical hysterectomy group and 11 (4%) of 307 women in the endometrial ablation group had at least one serious adverse event (adjusted OR 1·30, 95% CI 0·56–3·02; p=0·54; table 4). One woman in the laparoscopic supracervical hysterectomy group had two adverse events (infection and catheterisation). Other complications were rare, but there were more instances of immediate short-term voiding difficulties in the laparoscopic supracervical hysterectomy group (table 4).

18 (6%) of 307 women randomly assigned to endometrial ablation and two (1%) of 309 women randomly assigned to laparoscopic supracervical hysterectomy received further surgery during the follow-up period (table 4). The most common reason for further surgery was insufficient reduction in heavy menstrual bleeding following the index endometrial ablation procedure (12 patients). One woman who was randomly assigned to laparoscopic supracervical hysterectomy required a second procedure to remove the cervical stump because of ongoing pain and bleeding. A further seven women required unplanned further surgery because the index endometrial ablation procedure could not be completed on the first attempt. Hysterectomy was the second procedure on five occasions.

Women randomly assigned to laparoscopic supracervical hysterectomy had higher pain scores (0=no pain, 10=worst imaginable pain) in the first 2 weeks after surgery than those randomly assigned to endometrial ablation (marginal mean 3·39, SE 0·12 *vs* 2·48, 0·12); adjusted mean difference 0·92, 95% CI 0·59–1·24; p<0·0001; appendix pp 33–34) and more pain at 6 weeks (adjusted OR 1·43, 95% CI 1·05–1·96; p=0·025; appendix p 34), although the proportion of women with any pain symptoms was 157 (61%) of 256 assigned to laparoscopic supracervical hysterectomy versus 94 (39%) of 243 assigned to endometrial ablation (adjusted percentage difference 23, 95% CI 15–31) at 2 weeks and 89 (37%) of 241 assigned to laparoscopic supracervical hysterectomy versus 67 (29%) of 234 assigned to endometrial ablation (8·7, 1·6–15·8) at 6 weeks. At 2 weeks after the procedure, median pain scores were 1 (IQR 0–3) in the laparoscopic supracervical hysterectomy group versus 0 (0–2) in the endometrial ablation group; at 6 weeks median pain score was 0 (0–1) in both groups.

Women in the endometrial ablation group were able to return earlier to paid work (median 42 days, IQR 37–42 in the laparoscopic supracervical hysterectomy group *vs* 10 days, 7–14 in the endometrial ablation group; adjusted hazard ratio 0·23, 95% CI 0·18–0·30; p<0·0001), unpaid work (21 days, 17–25 in the laparoscopic supracervical hysterectomy group *vs* 7 days, 5–7 in the endometrial ablation group; 0·64, 0·57–0·73; p<0·0001), and sporting or social activities (42 days, 34–42 in the laparoscopic supracervical hysterectomy group *vs* 14 days, 14–18 in the endometrial ablation group; 0·48, 0·42–0·56; p<0·0001; appendix p 34).

At 15 months after randomisation, women in the laparoscopic supracervical hysterectomy group were more likely to recommend their treatment to a friend (263 [97%] of 271 women *vs* 246 [90%] of 280 women; adjusted OR 4·52, 95% CI 2·14–9·53; p<0·0001; appendix p 37).

The results of our sensitivity analyses did not alter our interpretation of the primary outcomes (appendix pp 30–32). Women with fibroids who were randomly assigned to laparoscopic supracervical hysterectomy reported better levels of satisfaction than those randomly assigned to endometrial ablation (OR 7·27, 95% CI 2·32–41·8; p=0·0019; appendix p 32). We observed no

	Laparoscopic supracervical hysterectomy (n=309)	Endometrial ablation (n=307)
Procedure received*		
Laparoscopic supracervical hysterectomy	291 (94%)	1 (<1%)
Endometrial ablation	12 (4%)	297 (97%)
Total hysterectomy	5 (2%)	5 (2%)
Hysteroscopy or polypectomy	1 (<1%)	4 (1%)
Uterine cavity length (cm)	8·38 (1·63) [259]	7·24 (1·97) [292]
Fibroids†		
Type 0 or 1 fibroid ≤3 cm	11 (4%)	11 (4%)
Type 2 fibroids ≤3 cm	9 (3%)	6 (2%)
Intramural or subserosal fibroids ≤3 cm	50 (17%)	10 (3%)
Not known	15	5
Duration of operation‡ (min)	114 (38) [306]	44 (23) [295]
Post-operative analgesia		
Paracetamol or ibuprofen	269 (87%)	226 (74%)
Oral opiate	136 (44%)	72 (23%)
Opiate injection	94 (30%)	46 (15%)
Time to discharge from operation (h)	21·5 (17·0–26·1) [306]	3·2 (2·1–5·1) [303]
Hospital stay >24 h (with reason if known)		
No	207 (68%)	287 (95%)
Yes		
Pain	30 (10%)	3 (1%)
Nausea or vomiting	2 (1%)	1 (<1%)
Social or geographical	13 (4%)	2 (1%)
Voiding problems	14 (5%)	1 (<1%)
Other reason	13 (4%)	4 (1%)
Reason unknown	27 (9%)	5 (2%)
Not recorded	3	4

Data are n (%), mean (SD), or median (IQR). N in square brackets indicates the valid N for continuous data where there were missing data at baseline. *38 women (19 in each group) did not undergo surgical treatment for heavy menstrual bleeding during the study period. †Fibroids detected at baseline scan and at hysteroscopy or laparoscopic supracervical hysterectomy procedure. ‡Time from entry to anaesthetic room to exit from operating room (min).

Table 3: **Surgical details for index procedure**

	Laparoscopic supracervical hysterectomy (n=309)	Endometrial ablation (n=307)
Any serious adverse event*	14 (5%)	11 (4%)
Infection	5 (2%)	5 (2%)
Pain	3 (1%)	4 (1%)
Catheterisation for longer than 72 h	3 (1%)	1 (<1%)
Conversion to hysterectomy	1† (<1%)	1 (<1%)
Readmitted for investigation of shortness of breath	1 (<1%)	0
Prolonged admission for observation only	1 (<1%)	0
Bladder injury	1 (<1%)	0
Other complications		
Voiding dysfunction	14 (5%)	2 (1%)
Consultation for pain	1 (<1%)	1 (<1%)
Haematoma	1 (<1%)	1 (<1%)
Blood loss >500 mL	1 (<1%)	1 (<1%)
Uterine perforation, inactive or blunt	1 (<1%)	3 (1%)
Pyrexia requiring antibiotics	3 (1%)	2 (1%)
Blood transfusion	0	1 (<1%)
Further operation by 15 months after randomisation	2 (1%)	18 (6%)

Data are (n%). *Numbers refer to participants, not events. †One woman randomised to laparoscopic supracervical hysterectomy received endometrial ablation but underwent conversion to total hysterectomy.

Table 4: **Serious adverse events and complications**

clinically or statistically significant differences in satisfaction or MMAS scores for any other of the subgroups on the basis of cavity length (≤8 cm *vs* >8 cm), age (<40 years *vs* ≥40 years), or symptoms of dysmenorrhoea (appendix p 32). We found no differences between baseline factors when comparing women who did and did not provide primary outcome data at 15 months (data not shown).

Discussion

This large randomised trial compared the two most commonly recommended surgical treatments for heavy menstrual bleeding (endometrial ablation and hysterectomy) in terms of patient-centred outcomes. At 15 months after randomisation, laparoscopic supracervical hysterectomy resulted in significantly higher satisfaction and better quality of life compared with endometrial ablation. Despite being a longer procedure with a slower recovery time, laparoscopic supracervical hysterectomy led to a greater improvement in menstrual blood loss, cyclical period-like pain, and dyspareunia, without incurring a higher risk of postoperative complications or precipitating bladder-related symptoms. The pragmatic multicentre nature of this trial is likely to enhance the generalisability of our findings.

Loss to follow-up in our trial was higher than anticipated. Although this is a limitation, we were able to achieve a response rate of more than 80% for the co-primary outcomes, and the overall results were unaffected in our sensitivity analyses. We were also unable to enforce a standard interval between randomisation and surgery. The NHS waiting list target of 3 months for routine operations prompted us to collect primary outcome data at 15 months after randomisation. Our expectation was that this strategy would allow a minimum of 12 months of follow-up but a tenth of women (balanced across the two study groups) faced delays in receiving treatment because of waiting list pressures or inability to attend hospital for surgery due to illness. In 14 (2%) of 616 participants, this delay resulted in an overlap between the 6-month post-surgery and 15-month post-randomisation questionnaires.

More subserosal and intramural fibroids were reported in the laparoscopic supracervical hysterectomy group. This finding was not entirely unexpected, as this strategy allows visual detection of small subserosal fibroids that can be missed at a baseline ultrasound scan. Although randomisation might have resulted in similar numbers of fibroids (both detected and undetected) in both groups, outcomes were better in those randomly assigned to laparoscopic supracervical hysterectomy.

Our results show a clear clinical benefit associated with both surgical techniques but measures of satisfaction, quality-of-life scores, and outcomes such as amenorrhoea, residual menstrual bleeding, and pelvic pain were more positive for laparoscopic supracervical hysterectomy compared with endometrial ablation. Specifically, only 3% of women in the laparoscopic supracervical hysterectomy group reported dissatisfaction compared with 13% of women in the endometrial ablation group. 69% of women assigned to laparoscopic supracervical hysterectomy achieved a maximum condition-specific quality-of-life MMAS score of 100, compared with 55% of those assigned to endometrial ablation. Although both procedures were associated with a reduction in symptoms of dyspareunia, improvement was more marked in women in the laparoscopic supracervical hysterectomy group, possibly because the uterus was removed. Thus, laparoscopic supracervical hysterectomy appears to be a more effective surgical treatment for heavy menstrual bleeding than endometrial ablation.

At recruitment, the physical and mental components of the SF-12 generic quality-of-life questionnaire in all participants with heavy menstrual bleeding were lower than normative values for healthy women of an equivalent age,[29] with mental health scores being particularly low. By 15 months after randomisation, the physical component in both trial groups and the mental component in the laparoscopic supracervical hysterectomy group had returned to normative values.[29] Although those allocated to endometrial ablation reported higher generic quality of life values at 6 weeks, possibly representing quicker recovery, by 15 months the visual analogue scale of EQ-5D and the mental component of SF-12 favoured those allocated to laparoscopic supracervical hysterectomy.

A previous individual participant data meta-analysis found total hysterectomy to be more effective than endometrial ablation, with dissatisfaction rates of 5% versus 15%,[12,13] although total abdominal hysterectomy was noted to be more invasive than endometrial ablation, with higher morbidity and prolonged recovery times.[12] The HEALTH trial has shown that outcomes after laparoscopic supracervical hysterectomy are similar to those achieved after total hysterectomy but with lower morbidity (<5%), which is similar to endometrial ablation. These relative benefits of laparoscopic supracervical hysterectomy should be offset against the longer total theatre time (almost 2 h compared with 45 min for endometrial ablation), early post-operative pain, greater duration of hospital stay (one in three women staying more than 24 h after the procedure compared with one in five for endometrial ablation), and prolonged recovery times (mean return to social or sporting activities of 42 days compared with 14 days).

The results of our predetermined subgroup analyses showed that the presence of fibroids was associated with poorer outcomes after endometrial ablation compared with laparoscopic supracervical hysterectomy. However, because of the small patient numbers and the differential detection of fibroids between the two groups, this result should be interpreted with caution. Age (<40 years *vs* ≥40 years), symptoms of dysmenorrhoea, or cavity length (≤8 cm *vs* >8 cm) did not have a significant effect upon clinical outcomes.

Both endometrial ablation and laparoscopic supracervical hysterectomy improved menstrual symptoms. 81% of patients having amenorrhoea after laparoscopic supracervical hysterectomy corresponds with longer-term published data,[24] but amenorrhoea in women after endometrial ablation was higher in our trial than the 40–50% reported in the literature.[7] Our results correspond with those reported in a systematic review and individual participant data meta-analysis of trials comparing total hysterectomy with endometrial ablation,[12] despite the fact that laparoscopic supracervical hysterectomy preserves the cervix and does not guarantee amenorrhoea. Two smaller randomised trials compared endometrial ablation with laparoscopic supracervical hysterectomy[17,18] and support our findings, although the time to discharge after laparoscopic supracervical hysterectomy was longer in our trial. This difference could reflect the culture within a public health-care system and traditional post-surgical expectations of patients, relatives, and clinical staff. The introduction of specific enhanced recovery programmes,[30] which were not a statutory part of postoperative care for laparoscopic supracervical hysterectomy in our trial, might reduce the length of hospital stay in the future. Despite a median pain score of 1 2 weeks after laparoscopic supracervical hysterectomy, return to normal activities was almost 6 weeks. This difference might reflect historical advice for allowed and expected convalescence after hysterectomy given by family doctors and nurses in the UK, and should be addressed through education and information packages to account for different approaches to undertaking this common operation.

This trial supports the previously reported reduced risk of complications with laparoscopic supracervical hysterectomy, which was comparable to endometrial ablation and much lower than for total hysterectomy. We found no evidence of bladder symptoms (urinary urgency, stress, or mixed incontinence) being negatively affected after laparoscopic supracervical hysterectomy.

The main disadvantage of laparoscopic supracervical hysterectomy compared with total hysterectomy is ongoing cyclical bleeding from the retained cervical stump. A Cochrane review of total versus subtotal hysterectomy suggested a cyclical bleeding rate of 5–10% after laparoscopic supracervical hysterectomy,[23] although a higher rate of 23% has been reported by Lieng and colleagues.[24] Despite routine electrosurgical cauterisation of the cervical canal after removal of the body of the uterus, in our trial 19% of women in the laparoscopic supracervical hysterectomy group continued to have light cyclical bleeding or spotting.

The higher number of reoperations in the endometrial ablation group is supported by the literature, which suggests that almost 20% of women undergoing endometrial ablation will have a hysterectomy within 5 years.[11] The number of subsequent surgeries after laparoscopic supracervical hysterectomy is not well known, although figures around 7% have been reported by 3 years.[24] The proportions of reoperations required will have an effect on cost-effectiveness and could influence patient preference for one treatment over the other.

Our trial reflects contemporary practice in the UK, where NICE defines heavy menstrual bleeding as excessive menstrual bleeding that affects a woman's quality of life and recommends the levonorgestrel releasing intrauterine system or an alternative medical treatment as the first step in women with no identified pathology or fibroids less than 3 cm in diameter.[8] When this strategy is unsuccessful, symptoms are severe, or pharmacological treatment is declined, women are referred to specialist care where the options include surgery (endometrial ablation or hysterectomy). As our eligible population comprised women with heavy menstrual bleeding referred by their general practitioners to gynaecology clinics, we expect our results to be generalisable to women who have been previously offered medical treatment. In this population, laparoscopic supracervical hysterectomy was found to be more effective than endometrial ablation for treating heavy menstrual bleeding without the risk of complications associated with total hysterectomy.[9,22] Thus, for gynaecologists with intermediate laparoscopic skills, laparoscopic supracervical hysterectomy provides an effective, minimally invasive surgical option that has the potential to reduce the number of open hysterectomies and their attendant complications and slow recovery times.[12]

As in this trial, most second-generation endometrial ablations are still done under general anaesthetic in an operating theatre, but the procedure can be done under local anaesthetic in an outpatient setting.[31] Newer, portable, small-diameter ablative devices with quick treatment times should encourage movement of endometrial ablation out of the traditional operating theatre. Our trial results could help inform greater choice for women with heavy menstrual bleeding seeking surgical treatment. Laparoscopic supracervical hysterectomy could be offered to women who want a general anaesthetic for their procedure and who are accepting of a longer recovery time. By contrast, endometrial ablation could be offered as a convenient outpatient procedure in women who are content to have local anaesthetic and who prioritise a less invasive procedure with quicker recovery over potentially reduced effectiveness.

Concerns have been raised about the potential risk of disseminating cells from undiagnosed uterine malignancy associated with the use of morcellators during laparoscopic hysterectomy in women with fibroids.[32,33] Risk factors highlighted by an updated estimate of leiomyosarcoma incidence at hysterectomy include age older than 50 years and the presence of larger fibroids,[34] both of which were exclusion criteria for the HEALTH trial. We were reassured by the absence of any histological abnormalities in this trial, including women with known fibroids of less than 3 cm in diameter. However, a high level of vigilance is required for hysterectomy where fibroids are present, and morcellation should be avoided if there are concerns of malignant changes within a fibroid. In the absence of accurate biomarkers, this decision would need to be based on morphological features or evidence of rapid growth. Morcellation within containment bags or removal of the uterus via a culdotomy are options for preventing tissue fragment dissemination. The risk of overlooking latent malignancy within a presumed fibroid is also relevant in all women undergoing endometrial ablation or any other conservative treatment for heavy menstrual bleeding where the uterus is preserved.

Laparoscopic supracervical hysterectomy was introduced because of its simplicity and potential to reduce surgical morbidity. However, further advances in instrumentation, improved training, and greater familiarity with laparoscopic surgery, combined with a greater appreciation of interventions to enhance surgical recovery might reduce these relative benefits of laparoscopic supracervical hysterectomy over total laparoscopic hysterectomy. Future trials comparing the two laparoscopic approaches to hysterectomy could help elucidate their relative advantages and disadvantages. Given the greater effectiveness of laparoscopic supracervical hysterectomy, albeit with longer operating times, hospital stay, and recovery time, a comprehensive heath economic evaluation of the two procedures over a medium-term to long-term time horizon is indicated. Such a study is currently being done by our group. Additionally, we intend to undertake longer-term follow-up of clinical and quality-of-life outcomes and further interventions for both study groups.

In conclusion, laparoscopic supracervical hysterectomy is more effective than endometrial ablation, without any additional risk of complications, but this treatment takes longer and is associated with increased time to full recovery. With an increasing number of options available for women with heavy menstrual bleeding it is important to explore how these techniques and the attributes associated with them—for example, care delivery systems, wish for amenorrhoea, and willingness to have treatment in a formal operating theatre or hospital setting—can influence patient choice. Methods of reducing recovery times and associated costs after surgery, including enhanced recovery interventions and packages of care, need further evaluation. Additionally, although endometrial ablation has been shown to be safe and acceptable under local anaesthetic, the reasons why most procedures are still undertaken in traditional theatre settings needs further investigation.

Contributors

KC, NWS, GS, JC, JH, RHa, KP, KM, JN, and SBh designed the study. KC, SBh, and SBr managed the study with support, input, and oversight from NWS, GS, JC, JH, RHa, KP, GM, SW, KM, and JN. NWS, GS, and RHe analysed the data, which was interpreted by all other authors. KC, SBh, NWS, and SBr wrote the first draft of the manuscript which was reviewed, modified, and approved by all other authors. All the authors vouch for the accuracy and completeness of the data reported and for the fidelity of the study to the protocol.

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Declaration of interests

JC reports grants and personal fees from Hologic, outside the submitted work; and membership of the Health Technology Assessment (HTA) Prioritisation Committee. JN declares grants from the University of Aberdeen and the University of Edinburgh during the conduct of the study and membership of the following National Institute for Health Research (NIHR) boards: HTA commissioning board; HTA commissioning sub-board (expression of interest); HTA funding boards policy group; HTA general board; HTA post-board funding teleconference; NIHR clinical trial unit standing advisory committee; NIHR HTA and efficacy and mechanism evaluation editorial board; and pre-exposure prophylaxis impact review panel. SBh is the Editor in Chief of HROpen and an Editor for Cochrane Gynaecology and Infertility. All other authors declare no competing interests.

Data sharing

Individual participant data collected for this trial and a data dictionary defining each field in the dataset will be made available to others; all available participant data will be de-identified. The protocol, statistical analysis plan, informed consent form, and ethics committee approval are available on request. To access data, a request should be submitted to the corresponding author with a scientific proposal including objectives. Written proposals will be assessed by members of the HEALTH trial steering committee and a decision made about the appropriateness of the request. Data will only be shared after a data sharing agreement is fully executed.

Acknowledgments

We thank the women who participated in the HEALTH study. We also thank Angela Hyde (Vice Chair of the Royal College of Obstetricians and Gynaecologists Women's Network until September, 2015, and co-applicant on the original grant application until October, 2016) for her contribution to the design of the participant facing documents and participation in trial meetings from the perspective of a patient, Jonathan Cook (statistician and co-applicant on the original grant application until April, 2014) for his contributions to the study design, Rebecca Bruce for her secretarial support and data management, members of the project management group for their ongoing advice and support of the trial, plus the independent members of the trial steering committee (Henry Kitchener [Chair], Patrick Chien, Barbara Farrell, and Isobel Montgomery) and data monitoring committee (Jane Norman [Chair], Peter O'Donovan, and Andy Vail), and the staff at the recruitment sites who facilitated recruitment, treatment, and follow-up of trial participants. The project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (project number 12/35/23). The Health Services Research Unit and the Health Economics Research Unit are funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates. The views expressed herein are those of the authors and not necessarily those of the NIHR or the UK Department of Health and Social Care.

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